



U.S. Department of Justice

*United States Attorney
District of Maryland
Northern Division*

*Allen F. Loucks
United States Attorney*

*Vickie E. LeDuc
Public Information Officer*

*36 South Charles Street
Fourth Floor
Baltimore, Maryland 21201*

*410-209-4800
TTY/TDD: 410-962-4462
410-209-4885
FAX 410-962-3091
Vickie.LeDuc@usdoj.gov*

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FOR IMMEDIATE RELEASE**

**FOR FURTHER
INFORMATION CONTACT
VICKIE E. LEDUC, AUSA
410-209-4885**

**NIH SUPPLIER AGREES TO PAY UNITED STATES \$ 7.2 MILLION TO SETTLE
DEFECTIVE PRODUCTS CLAIM**

Baltimore, Maryland - United States Attorney for the District of Maryland Allen F. Loucks announced today that Harlan, Sprague, Dawley, Inc. (HSD), an Indiana-based supplier of laboratory rodents, has agreed to pay the government \$7.2 million to settle government claims under the False Claims Act that it supplied NIH funded researchers with genetically non-conforming lab mice raised under two contracts it held with the National Institute of Aging (NIA).

Current and projected age-related research require the use of lab rodents with defined genetic characteristics. In order to assure that government sponsored researchers have a continuous supply of genetically defined rodents, NIA entered into two contracts with HSD in 1997 and 1998, respectively, that called for HSD to raise a number of genetically defined varieties of mice and rats over a nine-year period. HSD was to house and distribute the rodents to government-sponsored researchers performing age-related research. The genetic integrity of breeder rodents, whose offspring are sold to researchers, was to be monitored by HSD to assure that the offspring conformed to the known genetic profile of each breed.

Concerns over the genetic integrity one of the mouse strains raised under the contracts first surfaced in April of 2002 when it was discovered that starting in the spring of 1999, HSD's genetic testing of C57 breeder mice showed non-conformance to the known C57 genetic profile. This placed into question the genetic integrity of C57 mice housed in two of three HSD breeding facilities used for the two contracts. In addition, these tests were contrary to HSD's semi-annual progress reports for the contracts in which it represented to NIA that the genetic purity of its breeder rodents had been confirmed by genetic monitoring. Other than the C57 mice noted above, no other mouse and rat strains raised under these or other NIA contracts with HSD were affected by this problem.

NIA officials notified researchers using the potentially variant mice of these findings shortly after discovery. HSD and NIA provided replacement mice to researchers with ongoing projects in order to continue their studies. However, in some cases the validity of research using genetically variant mice was called into question.

The settlement represents full reimbursement to the government for the cost associated with raising genetically non-conforming mice, as well as the cost of government funded research negatively affected by the use of non-conforming mice. In addition, the settlement provides the government damages and penalties it may have obtained under the False Claims Act had it instituted suit under the Act.

"The genetic integrity of laboratory animals is critical in age-related research. We are pleased to announce this settlement which compensates the government for its time and effort associated with the use of these non-conforming mice, and maintains the integrity of NIA's age-related research programs," said United States Attorney Allen Loucks.

Enacted during the Civil War, the False Claims Act is the government's primary civil tool

to combat fraud and abuse in federal programs and procurement. The Act allows the government to recover triple the amount of its actual damages, plus a civil penalty of \$6,000 to \$11,000 for each false claim. Pursuant to the agreement, HSD does not admit that it violated the False Claims Act, nor does the government concede that its claims are not well founded.

The government's investigation was handled by Assistant United States Attorneys Michael A. DiPietro and Thomas F. Corcoran and investigative auditor Mary G. Hammond, in conjunction with the Department of Health and Human Services-Office of Inspector General.